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New business practices drive down pharmaceutical costs

Pharmaceutical companies can stay focused on R&D as they outsource the actual manufacturing to contract manufacturing organizations, which is further enhanced by partnering with specialists capable of controlling operational variabilities in temperature and humidity - leading to improved efficiency and compliance

Given the cost of developing a new drug and bringing it to market, the high level of R&D expenditures in the pharmaceutical industry are accelerating cost optimization throughout the supply chain.

It's no secret that the most effective strategies with the highest benefit-to-cost ratio involve outsourcing, giving pharmaceutical companies the freedom to prioritize their own internal capacities and enhance process efficiencies.

Pricing pressure, emerging markets, supply and distribution challenges are accelerating partnerships between traditional "pharma" and the rapidly expanding outsourcing capabilities of contract manufacturing organizations (CMOs). Just like their pharmaceutical clients, CMOs can control capital outlays by leveraging Aggreko's specialized capabilities.

REDUCING OPERATIONAL AND FIXED COSTS

The U.S. pharmaceutical industry spent over $1 billion on energy in 2018. As energy costs increase, more companies are investing in measures to enhance the reliability and energy efficiency of temperature and humidity control systems. Considered individually, each measure may offer small savings, but combined they add up to significant savings and short payback periods, which is why many facilities have been scheduling system upgrades, including their heating, ventilation and air conditioning (HVAC) assets. However, the cost of buying the newest chilling, dehumidification and other climate control systems can become much higher than actual energy costs.

Energy intensive equipment and their operational costs can be avoided in many circumstances, which is why many of the pharmas utilize the facilities of their CMO partners for manufacturing operations. In fact, major pharmaceutical companies now outsource up to 60 percent of their manufacturing to CMOs that provide comprehensive services from drug development through manufacture. Throughout the supply chain, whether a major pharmaceutical company or one of its CMO partners, having an external partner is more efficient than investing in a lot of fixed assets, particularly with HVAC and other systems needed for temperature and humidity control.

Just like their pharma clients, many of the top CMOs have evolved into becoming "new product introduction" companies with their own brand that includes finished dosage form (FDF) manufacturing and active pharmaceutical ingredient (API) production. For example, when the CEO of a New Jersey based CMO with 35 facilities was questioned about outsourcing in a recent interview in the trade press, he noted an accelerated transition by CMOs in terms of more capable equipment, processes and facilities, which he says will continue. During this transition, low risk, cost-efficient temporary HVAC and other humidity and temperature control solutions must be available.

FLUCTUATIONS

Whether the challenge is high or low relative humidity, or a fluctuation of both conditions, medical products can be negatively affected. For example, low relative humidity promotes the build up of static charges, especially below 40%, which could cause drugs to stick to each other and cause packaging problems. Dry conditions also affect the behavior of solvents and lead to moisture losses in products. The need for humidity controls also important within machinery. Pharmaceutical and CMO manufacturing facilities may also use HVAC systems to control the environment in clean rooms to ensure worker comfort.

Aggreko's temperature and humidity control systems help the industry comply with production guidelines while also reducing capital expenditure outlays, as a facility only uses the equipment it requires on an as-needed basis without worrying about maintenance- and service contract-related expenses. Every production line, research lab and warehouse in the pharmaceutical industry needs to be maintained under carefully controlled conditions. A fluctuation of just one or two degrees throughout a 24/7 batch or continuous process can quickly lead to non-compliant product, which is why reliability of temperature control equipment is crucial. For example, a controlled sterile environment needs

to be completely free of dust, microbes, or trace chemicals that can affect product specifications, reinforcing the onus on reliable HVAC systems, which is why the role of the cold chain continues to grow in importance insofar as keeping sensitive, high-throughput pharma processes within a designated temperature range.

Here, effective temperature control systems provided by Aggreko minimize capital investment as recently seen at a CMO facility in Virginia, where the CMO reached out to Aggreko to provide an ultra-low temperature process chiller for their distillation column batch process. This CMO had contracts for only a one-year duration and saw the economic benefit of utilizing temporary ultra-low temperature chillers versus the high CAPEX required for a permanent unit. This allowed the facility to have better cash flow to support operation and better control of their utility systems as production schedules of the plant fluctuates up and down. Aggreko provided all the engineering and design and has since scaled the chillers on-site with the CMO's production schedule utilizing over 1,200 tons of installed temporary cooling.

Unique facility requirements benefit the production of pharmaceutical products leveraged by tight specifications. Pharmaceutical industry regulations, which have the force of law, require that manufacturers, processors, and packagers of drugs take proactive steps to ensure safe and effective products. The industry's adherence to current Good Manufacturing Practices (cGMP) establishes a predicate that, just like permanent units, temporary or emergency HVAC systems should also incorporate unique capabilities, depending on the challenges.

PRODUCT DETERIORATION

While the cost of a temporary HVAC supply system may be compared with the impending cost of product deterioration (should temperatures or airflow go out of control), it is frequently the skills and experience of HVAC technicians that guarantee the performance of temporary HVAC equipment. If permanent HVAC systems break down or require maintenance, they need to be replaced quickly with chillers, air-handling systems, etc., until a permanent solution is activated.

The toll on temperature-control equipment is frequently the source of putting pharmaceutical production and quality levels at risk. For example, with many pharmaceutical operators planning on shutting down their permanent HVAC system for maintenance or upgrades, the ability of a temporary HVAC system's ability to mitigate high relative humidity (RH) levels becomes the focus of the service insofar as guarantees, cost, contract obligations, etc.

In any case, dehumidifiers are expected to control RH to lower levels, but to what extent? More facilities are requiring RH of about 50% by cooling the air to the appropriate dewpoint temperature. This requirement results from the industry incorporating higher volumes of hygroscopic (moisture absorbing) material such as polyvinyl-pyrrolidone (PVP) into their formulations. PVP serves as a synthetic polymer vehicle for binding, dispersing and suspending drugs. In these instances, tighter adherence to humidity control reinforces the importance of working with a supplier of temporary HVAC equipment supported with engineering and risk aversion capabilities, such as remote monitoring. In some manufacturing operations where these bespoke hygroscopic materials are processed, the ambient RH requirement may be as low as 30%, further adding to the risk of not meeting product specifications.

HVAC

An essential step in the HVAC design process, whether on a temporary or emergency basis, is coordination with electrical design teams. The sizing of temporary generators can be greatly affected by motors required on emergency power from the HVAC system. Blowers, sensing devices and other equipment that require interlocks must also be factored into the engineering solution. The application of HVAC systems consisting of dampers, supply and exhaust fans, humidifiers, dehumidifiers, heating and cooling coils, ducts, etc., are closely supervised by the FDA and other global regulatory standards.

In addition, energy efficiency measures incorporated into HVAC systems must conform to current cGMP. Although cGMP allows for new HVAC techniques, the additional time required, and the risks associated with a delay in approval of building plans, may have led some drug companies to stick with less energy-efficient designs that eventually need to be replaced. In many cases, this replacement is required "sooner than later." With this consideration, Aggreko technicians work with the drug manufacturer to understand the operation, assess equipment needs and suggest the best way to keep the process running safely while essential maintenance is performed.

COOLING SYSTEM SWAP OUT

GlaxoSmithKleine (GSK), a global leader in the production of pharmaceuticals, vaccines and consumer health care, were about to swap out their cooling system at the Rixensart vaccine production site and needed temporary cooling. But because vaccine production is such a precise process, the system had to be controlled and accurate.

They needed power that could be controlled within a 50 kW range starting from zero; frequency controlled pumps with data pressure measurement; and a connected alarm system that would alert if any of the vaccine environments strayed outside their strict parameters. They also needed the entire system to drop to 45 decibels at night because they were right next door to a nature area.

Four WCHP 250 chillers and two WCC 800 chillers were arranged in a cascading set up, along with five 350 kVA generators. An expert controller was also positioned on-site to control the system and ensure power outputs met required specifications. This combination of chillers and generators was chosen because it provided the most efficient means to deliver the power needed and still provide the precise control that GSK needed. The system was hooked up with an alarm system to notify the customer if the vaccine cultures strayed outside strict parameters.

CONCLUSION

Even a small change to the structure of a pharmaceutical product during the manufacturing process can significantly impact function. Against this backdrop, CMOs give pharmaceutical/medical manufacturers the freedom to prioritize their own internal capacities and enhance process efficiencies. However, a recent Frost & Sullivan report indicates that the overall satisfaction and likelihood of contract renewal is fairly low – around 40 to 50 percent across all product types. To minimize vendor switching, CMOs would do well to consider the proven capabilities offered by Aggreko as many of these CMO facilities upgrade their capabilities to become contract developmental manufacturing organizations (CDMOs), that may include R&D. Recognizing these opportunities, the growing number of CMOs and CDMOs have turned to Aggreko's temporary temperature and humidity control solutions to maintain compliance and reduce variabilities in operational cycles.

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